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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,165	01/30/2004	Euljoon Park	A04P1011	7794

36802 7590 03/28/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/769,165	PARK ET AL.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of the amendments received 11 January 2006.

Claim Rejections - 35 USC § 102

2. Applicant's arguments, filed 11 January 2006, with respect to the rejections of claims 1-21 under Park (U.S. 6,881,192) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection is made in view of Katz et al (U.S. 6,580,944).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park (U.S. 6,881,192) in view of Katz et al (U.S. 6,580,944). Regarding claims 1, 2, 9 and 13, Park discloses (column 1, lines 52-56) "an implantable cardiac device is programmed to detect an episode of sleep apnea and measure the duration of the episode. In one implementation, the implantable cardiac device initially confirms that a patient is at rest using an activity sensor or a posture sensor." The examiner considers this to be sensing circuitry to sense whether a patient is at rest, the sensing circuitry further being operative to sense cardiac electrical activity. Park further discloses (column 1, lines 57-60) the implantable cardiac device "then monitors a respiration-related parameter (e.g., respiration rate, tidal volume, minute ventilation) or oxygen-

related parameter (O_2 saturation, SO_2, O_2 pressure) to determine when the patient is experiencing a sleep apnea episode." The examiner considers this to be a sleep apnea detector to detect when a patient, who is at rest, is experiencing an episode of sleep apnea. Park discloses (column 11, lines 14-20) a process in which "respiration parameters used to detect hyperventilation and subsequent apnea conditions were used. This process for detecting apnea is effective for the case of central sleep apnea. Process (500) employs an O_2 sensor reading, such as O_2 saturation, as a way to detect apnea conditions in the case of obstructive sleep apnea." The examiner considers this to be differentiating between central sleep apnea and obstructive sleep apnea based on the cardiac electrical activity. Park fails to teach using the cardiac electrical signal that is monitored as a basis for diagnosis of central or obstructive apnea. Katz however discloses (column 7, lines 33-48) "air flow monitor (16) provides an input to the chaotic processor (14). It has been found that a measurement of a single cardio-respiratory function can provide sufficient data for making a diagnosis. In some situations it may desirable to use a measurement of another cardio-respiratory function exclusively of the air flow measurement or as a complement to the air flow measurement. The results from the complementary measurement could then be used to corroborate the signals from the air flow monitor. Consequently in FIG. 1 additional monitors are shown in phantom. These include an ECG (44) that measures electrical heart activity; a heart rate monitor (45) that measures heart rate." Park and Katz both teach methods of diagnosing obstructive or central sleep apnea based on physiological signals. Therefore it would have been obvious of ordinary skill in the art at the time of the

invention to modify Park's implantable cardiac device with Katz's electrical heart activity monitor in order to corroborate a diagnosis of sleep apnea using more than one physiological parameter.

Regarding claims 3 and 9, Park discloses (column 7, lines 16-18) "the activity/position sensor may be implemented in many ways, including as a 3 dimensional DC accelerometer."

Regarding claims 4, 5, 10, 14 and 15, Park discloses (column 7, lines 52-57) "signals generated by the position sensor, MV [minute ventilation] sensor, and O_2 sensor are passed to the microcontroller for analysis by the sleep apnea detector. Such signals can be used to determine whether the patient is at rest, whether the patient is experiencing an episode of sleep apnea, when to begin measuring a duration of a sleep apnea." The examiner considers this to be a sensing circuit configured to sense a respiration-related signal, and a sleep apnea detector that detects the episode of sleep apnea based upon the respiration-related signal. The respiration-related signal is a signal indicative of minute ventilation, and of O_2 saturation.

Regarding claim 6, Park discloses (column 9, lines 40-45) "the device will be described as monitoring a respiration signal representative of tidal volume. The thresholds TH_{HV} and TH_A are set to predetermined amplitude levels of the tidal value that are suggestive of hyperventilation and sleep apnea." See Figure 4. The examiner considers this to be using amplitude modulation of intracardiac electrogram waveforms to differentiate between the central sleep apnea and the obstructive sleep apnea. While Park remains silent on whether the differentiation is between central and obstructive sleep apneas, a device employing amplitude modulation, as taught by Park, would inherently be able to distinguish between central and obstructive sleep apnea based on the data gathered. See Figure 5.

Regarding claims 7, 12 and 16, Park discloses (column 11, lines 62-64) "the device can be optionally configured to administer pacing therapy in response to detection of the sleep apnea episode." See Figure 5. The examiner considers this to be a sleep apnea therapy module to administer different pacing therapy depending upon whether the sleep apnea detector classified the sleep apnea as central apnea or obstructive sleep apnea.

Regarding claims 8 and 13, Park discloses (column 5, lines 55-57) "cardiac signals are supplied to an analog-to-digital (A/D) data acquisition system, which is configured to acquire intracardiac electrogram signals." The device also has the other claimed features, as explained above.

Regarding claim 11, Park discloses (column 11, lines 14-20) a process in which "respiration parameters used to detect hyperventilation and subsequent apnea conditions were used. This process for detecting apnea is effective for the case of central sleep apnea. Process (500) employs an O_2 sensor reading, such as O_2 saturation, as a way to detect apnea conditions in the case of obstructive sleep apnea."

The examiner considers this to be differentiating between central sleep apnea and obstructive sleep apnea based on the cardiac electrical activity.

Regarding claim 12, Park discloses (column 4, lines 8-10) the device "further includes an atrial pulse generator that generates pacing stimulation pulses." Regarding claims 17-21, in view of the structure as disclosed by Park, the method of operating or using the device would be obvious because it is the normal and logical means by which the device can be used.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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